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TITLE: Facilitating smoking cessation and preventing relapse in primary care: Minimizing weight gain by reducing alcohol consumption

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13. SUPPLEMENTARY NOTES

14. ABSTRACT A randomized controlled trial was conducted evaluating two smoking cessation interventions for use in primary care settings. Both included the nicotine patch and buproprion (Zyban) if desired. The Brief Counselor Assisted Program (BCAP; 2 in person and 2 telephone counseling sessions) combined motivational interviewing and behavioral counseling with an emphasis on reducing alcohol consumption to minimize weight gain. Participants in the Self-Guided Program (SGP) received a pamphlet discussing change strategies for tobacco cessation, minimizing weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up were randomized to receive no further counseling or an in person booster session focusing on obstacles to change. There were 317 participants, 158 in BCAP and 159 in SGP. Followup was completed on 92.1% of participants at 3-months, 90.85% at 6-months, and 88.33% at 12-months. Of those found at 3-months, 46.8% of BCAP and 34.4% of SGP participants were non-smokers (p=.031). The difference lost significance when an intent to treat analysis was conducted, but more sensitive analyses (e.g., logistic regression) may still find the difference to be significant. Weight loss and alcohol reduction changes at 3 months were in the predicted direction, but will need to be statistically evaluated by multivariate methods. The current focus is on statistical analyses and dissemination of findings.

15. SUBJECT TERMS
smoking cessation, weight, alcohol, stepped care, primary care

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Annual Report Award Number W81XWH-05-2-0015

Introduction

This report summarizes progress made on Award Number W81XWH-05-2-0015 for the project year from December 27, 2009 through December 26, 2010. The project, “Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption,” involves developing and testing a brief smoking cessation intervention for use in primary care settings. The intervention is intended to help participants stop smoking cigarettes and stay quit by use of motivational interviewing, behavioral counseling and nicotine replacement therapy with an emphasis on reducing alcohol consumption as a strategy for minimizing weight gain related to smoking cessation. Participants are randomly assigned to one of two groups: a Brief Counselor Assisted Program (BCAP), or a Self-Guided Program (SGP), with the nicotine patch and buproprion (Zyban) available to all participants. Participants in the BCAP attend two 30-minute clinic appointments and have two counseling sessions by phone over a period of 8-10 weeks, where tobacco cessation skills are integrated with weight and alcohol reduction strategies. Participants in the SGP receive, in addition to the medication, a pamphlet discussing the most effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up, blocked by original group assignment, are randomized either to receive no further counseling or to attend one clinic booster session focusing on dealing with their individual obstacles to change. All participants are followed up for 12 months. The study addresses three research questions: (1) Does an alcohol reduction strategy designed to minimize weight gain produce higher smoking cessation rates than a control treatment? (2) Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse? (3) Does providing a stepped care intervention (booster) for participants who initially are unsuccessful at stopping improve long-term tobacco cessation rates?

Body

The original Statement of Work was itemized for each investigator and consultant and by necessity, therefore, included considerable redundancy. To make this report better organized and easier to follow, we first discuss progress made toward objectives shared among the investigators. Following that, individual Statements of Work will be presented. The project was approved for a two-year no cost extension in April, 2008.

During the past project year our focus was on double entering and cleaning the large amount of data accumulated, and undertaking the formal analyses of the completed and verified data set. Our final sample consists of 317, with 158 in the BCAP group and 159 in the SGP group. To attain this sample we had contact with 1,391 total individuals, and of those we screened 1,296 (48 were not screened because they first asked if we offered Chantix, and when they found out we did not offer it they withdrew from consideration because they could receive Chantix through the smoking cessation

program at the base Health and Wellness Center; 47 left initial contact information but never responded to repeated attempts to contact them). The major reasons for screening out were not enough alcohol consumption (549 of 961 total screenouts, or 57%), and wanted Chantix (42), followed by a variety of other reasons such as not wanting to be further contacted. Beside wanting Chantix, which could not be made available because it would have introduced a new medication midway through the trial and possible adverse side effects of Chantix were under investigation at the time, the major reason for screening out was not meeting the alcohol consumption criteria (≥ 4 drinks per week). This was unexpected because, as stated in out original grant proposal, the 2002 DoD Survey of Health-Related Behaviors among Military Personnel reported that, among other things, more than 40% of DoD personnel drank 5 or more drinks at least monthly. In screening for our project, however, more than half of the screenouts resulted from insufficient alcohol consumption. As noted previously, during screening there may have been underreporting of alcohol consumption because our informed consent form was required to include the statement "complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities." This is in contrast to surveys for which respondents typically can remain anonymous. In any event, our final sample was smaller than we had wished but is adequate to test our group comparison.

A strong point of the implementation of the project is that our rate of retrieving data for follow-up was excellent, especially for a large scale study. At 3-month follow-up, we obtained data on 92.10% of the participants, consisting of 94.97% of the BCAP group and 89.24% of the SGP. Of those found, 46.8% of the BCAP group and 34.4% of the SGP group were non-smokers at three months. This difference was statistically significant ($p = .031$) when evaluated for the 92.1% found for follow up, but it was no longer significant ($p = .095$) when a bare bones intent-to-treat analysis was performed (i.e., every case for which data were not found was considered to be a failure). We anticipate that the finding may still be significant when more sensitive analyses (such as logistic regression analyses) currently underway are completed, as the inclusion of other variables is likely to reduce the error variance somewhat. We also are conducting our formal analyses of changes in weight and in drinking at follow-up periods. Preliminary analyses of 3-month follow-up data had indicated that the SGP group had gained a mean of 2.22 pounds while the BCAP group had gained a mean of 0.84 pounds. Likewise, the SGP group had reduced its drinking a mean of 2.86 drinks per week (29.1% of baseline) while the BCAP group had reduced its drinking by a mean of 4.29 drinks per week (41.7% of baseline). Although both of these differences were in the expected direction in the preliminary analysis, the time X group interaction failed to reach significance. For weight, there was a significant time effect (baseline to 3-mos), $F(1,286) = 8.05$, $p=.005$, but no interaction with condition $F=2.63$, $p=.106$. Similarly, for drinks per week there was a significant time effect (baseline to 3-mos), $F(1,289) = 73.79$, $p<.001$, but no interaction with condition $F=2.92$, $p=.089$. More sensitive analyses currently in progress may yield significant differences as we control for other variables.

The follow-up retrieval rates for the 6-month and 12-month follow-ups were excellent, as studies often retrieve data on only 70%-80% of cases in long-term smoking cessation follow-up. In our study, 6-month follow-up data were collected from 91.14% of the BCAP group and 90.57% of the GSP group, for an overall rate of 90.85%. For the 12-month follow-up, data were collected from 89.24% of the BCAP group and 87.42% of the GSP group, for an overall rate of 88.33%.

Because our emphasis was on data entry and cleaning and planning the formal analyses, only one presentation of findings occurred during this project year. That presentation was at the annual meeting of the American Psychological Association and involved presentation of the findings discussed above. A copy of that presentation appears as an appendix to this report. Our emphasis during the coming project year will be on completing the data analyses and presenting findings, with an emphasis on submitting manuscripts for publication. Beyond the group comparisons there are several other central analyses being conducted (e.g., examining weight gain and alcohol reduction) as well as several ancillary but important analyses (e.g., the possible role of depression as a moderating variable). Because high quality journals recommend against piecemeal publication (i.e., investigators submitting a number of manuscripts describing different findings from the same study) and prefer manuscripts that provide most or all important findings in one major paper, we have not submitted manuscripts addressing preliminary, partial, or incomplete results. We realize this approach can be controversial, but we agree with the editors of major journals that a high quality relatively complete article is preferable and has more impact than presenting findings in separate isolated reports (i.e., that quality should take precedence over quantity). (The Principal Investigator for this project has been Editor of a major top tier journal—the *Journal of Consulting and Clinical Psychology*—and has served five terms as Associate Editor for journals, and this has created a distinct familiarity with the reasons to discourage piecemeal publication.) To facilitate completing the analyses and reporting, we are presently preparing a request for modification to our award that will only require internal re-budgeting and will not affect the Statement of Work. The request will concern how to allocate a small amount of savings achieved during the past project year so as to facilitate completion of the analyses and publication of results.

The following completes the body of this report in a more standard format, reporting achievement of benchmarks approved in the May, 2008 revision of the Statement of Work for this project.

Mark B. Sobell, Ph.D.
Nova Southeastern University

1. Hire project team members: Y01 M03 Completed
2. Finalize formal protocol, manuals: Y01 M09 Completed
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
4. Monitor compliance with, and integrity of, the treatment protocols: Completed
5. Monitor the quality control of all the data collection required for the project: Completed

6. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
7. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: Completed
8. Develop and implement plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Completed
9. Generate the final manuscripts of study results: Y05-07 M12 Ongoing
10. Disseminate results and materials produced by the study: Y05-07 M12 Ongoing

Linda C. Sobell, Ph.D.
Nova Southeastern University
1. Hire project team members: Y01 M03 Completed
2. Finalize formal protocol, manuals: Y01 M09 Completed
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
4. Train personnel in project intervention: Y01 M12 Completed
5. Monitor compliance with, and integrity of, the treatment protocols: Completed
6. Monitor the quality control of all the data collection required for the project: Completed
7. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
8. Oversee the conduct of project follow-up: Y04-05 M12 Completed
9. Generate the final manuscripts of study results: Y05-07 M12 Ongoing
10. Disseminate results and materials produced by the study: Y05-07 M12 Ongoing

Lt Col Alan Peterson, Ph.D.
Wilford Hall Medical Center
1. Review/coordinate IRB approvals: Y01 M09 Ongoing
2. Hire project team members: Y01 M03 Completed
3. Secure office space for WHMC grant staff: Y01 M09 Completed
4. Finalize formal protocol, manuals: Y01 M09 Completed
5. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
6. Coordinate the training of phone counselors this project: Y01 M12 Completed
7. Provide weekly clinical supervision of phone counselors and monitor compliance with, and integrity of, the treatment protocols: Completed
8. Monitor the quality control of all the data collection required for the project: Completed
9. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
10. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: Completed

11. Supervise WHMC military and grant staff in assessment and intervention procedures:Y04 M12 Completed
12. Assist in developing and implementing a plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Completed
13. Generate scientific conference presentations of study preliminary results: Y05-07 M12 Ongoing
14. Review/coordinate IRB amendments and annual reports: Y05-07 M12 Ongoing
15. Generate the final manuscripts of study results: Y05-07 M12 Ongoing
16. Disseminate results and materials produced by the study: Y05-07 M12 Ongoing

Maj Christopher Hunter, Ph.D.
Wilford Hall Medical Center
1. Revise intervention manuals: Y01 M09 Completed
2. Assist in finalization of assessment instruments Y01 M09 Completed
3. Assist in training of military and grant staff to work in the primary care setting Y01 M09 Completed
7. Generate manuscripts of study results: Y05-07 M12 Ongoing

Maj Christine Hunter, Ph.D.
Wilford Hall Medical Center
1. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed
2. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 1. Completed
3. Assist in training of telephone counselors: Y01 M12 Completed
Assist in weekly supervision of phone counselors: Completed
4. Generate manuscripts of study results: Y05-07 M12 On-going

Capt Jeffrey Goodie, Ph.D.
Wilford Hall Medical Center
1. Finalize formal protocol manuals: Yo1 M09 Completed
2. Assist in training staff to work in primary care setting: Y012 M12 Completed
3. Generate manuscripts of study results: Y05-07 M12 Ongoing

Keith Haddock, Ph.D.
University of Missouri, Kansas City
1. Provide consultation on development of data base for study and computerize data entry: Y01 M12 Completed

Carlos Poston, Ph.D.

University of Missouri, Kansas City
1. Provide consultation on development of data base for study and computerize data entry: Y01 M12 Completed

Timothy Baker, Ph.D.
University of Wisconsin, Madison
1. Provide consultation on smoking cessation treatment protocol and development of data base: Y01 M12 Completed
2. Help monitor integrity of study implementation: Y03 M06 Not needed
3. Provide consultation on data analysis strategies: Y07 M12 Ongoing
4. Provide consultation on interpretation of results: Y07 M12 Ongoing

Lt.Col. Ann Hryshko-Mullen, Ph.D. (Brought forward from the January 2009 annual report) Dr. Hryshko-Mullen is a Wilford Hall Medical Center staff member added to the research team after the Permanent Change of Station (PCS) of Capt. Jeffrey Goodie, Ph.D. in August 2005. Dr. Mullen is the Chief of the Clinical Health Psychology Service at Wilford Hall.
1. Maintained Wilford Hall office space for all grant staff personnel: Completed
2. Coordinated with Lackland AFB Tobacco Cessation Program to limit any overlap or conflict with proposed study and ongoing Tobacco Cessation programs: Completed
3. Manuals: Completed
4. Assist in training staff to work in primary care setting: Completed
5. Generate manuscripts of study results: Y05-07 M12 Ongoing

Sangeeta Agrawal, M. Sc.
1. Conduct statistical analyses, consult on interpretation of findings: Y06-06 M12

Key Research Accomplishments.

- Achieved a very high data retrieval rate for follow-up (3-month follow-up, 92.10% of all participants; 6-month follow-up, 90.85% of all participants; 12-month follow-up, 88.33% of all participants).
- Preliminary analyses of 3-month outcomes based on data from the 92.10% of all participants found for follow-up showed that 46.8% of the experimental (BCAP) group and 34.4% of the control (SGP) group were non-smokers. This difference was statistically significant ($p = .03$) but when analyzed using a conservative intent-to-treat analysis (i.e., all cases not found for follow-up were assumed to be still smoking) the difference was not significant ($p = .095$). Ongoing more sensitive analyses are currently underway.
- Weight loss and alcohol consumption reduction means were in the direction predicted buy the study hypotheses but did not attain significance when analyzed in isolation. The control group gained a mean of 2.22 pounds while the experimental group gained a mean of 0.84 pounds. The control group reduced its drinking a mean of 2.86 drinks per week (29.1% of baseline) while the experimental group reduced its drinking by a mean

of 4.29 drinks per week (41.7% of baseline). Ongoing more sensitive analyses are currently underway.

Reportable Outcomes

During the reporting period, one poster presentation of project results occurred:

Sobell, M.B., Sobell, L.C., Peterson, A.L., Hunter, C.L., Hunter, C.M., Brundige, A., & Goodie, J.L. (2010, August). Facilitating Smoking Cessation by Reducing Alcohol Consumption. Poster presented at the Annual Convention of the American Psychological Association, San Diego, CA.

Conclusions

Although the final sample size was less than our target, our rates of retrieval of follow-up data were excellent. Preliminary evaluations of short-term outcomes (3-month) showed a significantly higher smoking cessation rate for the experimental (BCAP) group than the control (SGP) group when only the 92.10% of participants for whom follow-up data were gathered were included in the analyses. When participants for whom data were missing were considered to all be still smoking, the group difference was no longer significant, but this was largely because there was a higher follow-up rate for the experimental group than the controls. At 6-month and 12-month follow-ups the difference in find rates between the groups is much less and therefore those analyses will be less affected in an intent-to-treat approach analysis. Also, differences between the groups in terms of amount of weight gain and reduction in alcohol consumption were in the direction of the hypotheses in preliminary analyses but were not significantly different using isolated analyses. When these factors are combined in more sophisticated analyses such as logistic regression analyses and mediation and moderation analyses, they may reach significance as the error variance is likely to be greatly reduced. Final analyses using advanced statistical techniques are currently in progress. If in these analyses statistical significance is attained, the findings will add another tool to the arsenal in terms of ways to facilitate smoking cessation. This is especially important for the military where smoking affects readiness and where concern about weight gain related to smoking cessation can be an obstacle to attempting to stop smoking. In this regard, a number of materials developed for use in the experimental condition are available and could be easily disseminated.

References

See reportable outcomes. No journal articles at this time.

Appendices

Sobell, M.B., Sobell, L.C., Peterson, A.L., Hunter, C.L., Hunter, C.M., Brundige, A., & Goodie, J.L. (2010, August). Facilitating Smoking Cessation by Reducing Alcohol Consumption. Poster presented at the Annual Convention of the American Psychological Association, San Diego, CA.

Facilitating smoking cessation by reducing alcohol consumption

Mark B. Sobell[1], PhD, Linda Carter Sobell[1], PhD, Alan L. Peterson[2], PhD, Christopher L. Hunter[3], PhD, Christine M. Hunter[4], PhD, Antoinette Brundige[2], MA, Jeffrey L. Goodie[5], Ph.D.

1. Nova Southeastern University, 2. University of Texas Health Science Center at San Antonio, 3. Tricare Management Activity, 4. National Institute of Diabetes & Digestive & Kidney Diseases, 5. Uniformed Services University of the Health Sciences

Introduction

- **Concern about weight gain is a well established barrier to smoking cessation.**
- **In the military, concern about weight gain after quitting is of heightened concern because excessive weight can result in being unfit for service.**
- **This randomized clinical trial targets smoking cessation and minimizing weight gain in patients seen in military primary care settings.**
- **A unique feature of this study is counseling to reduce alcohol consumption to minimize weight gain after smoking cessation.**
- **Reduction of alcohol consumption is also included as a treatment component because it is highly correlated with smoking relapse and may increase weight gain due to its relatively high caloric value.**
- **It is expected that participants who reduce their alcohol use will have a higher cessation rate and a lessened risk of relapse to smoking compared to participants who do not receive such counseling.**

Treatment Conditions

Brief Counselor Assisted Program (BCAP): **Tobacco cessation procedures integrated with weight and alcohol reduction strategies, including nicotine replacement therapy (NRT) and Bupropion SR (Zyban). Two clinic sessions and two phone sessions over 8-12 weeks.**

Pharmacotherapy plus Pamphlet (PP): Self-help pamphlet describing how to implement effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to deal with possible relapses. NRT and Bupropion SR provided.

Booster: Those who had not stopped smoking at the 3-month follow-up, half, blocked by initial treatment condition, were randomly assigned to receive a booster session on overcoming barriers .

Participants

- **Primary care clinics at Wilford Hall Medical Center (San Antonio, TX) were the primary source of participants.**
- **All participants were eligible military medical beneficiaries.**
- **Inclusion Criteria: ≥ 21 years of age, smoke a mean of ≥ 5 cigarettes/day for past year, consume a mean of ≥ 4 standard drinks/week, concerned about weight gain, plan to stay in area ≥ 1 year.**
- **Exclusion criteria: Pregnant, trying to become pregnant, breastfeeding; health conditions that contraindicate cessation medication; used weight loss medication within past 6 mos.; at base temporarily; recent or current major depression; DSM-IV alcohol use disorder; other medical contraindications.**

Participant Characteristics

Variable	Group	
	BCAP (*n* = 158)	PP (*n* = 159)
Mean (*SD*) yrs age	37.3 (13.1)	37.6 (12.9)
% Male	69.6	72.3
% Married	62.7	58.5
% White/Caucasian	72.2	68.6
M (*SD*) yrs education	13.7 (1.7)	13.5 (1.8)
% Active duty	63.3	64.8
M (*SD*) Fagerström score	3.7 (2.2)	4.0 (2.1)
M (*SD*) yrs reg. smoker	18.1 (12.9)	18.7 (13.0)
% Health most important reason	79.1	76.7
M (*SD*) no. past quit attempts	6.1 (6.0)	5.9 (6.2)
% Definitely quit next 2 wks.	44.9	47.8
% Def. be nonsmoker in 6 mos.	40.5	43.4
% Def. quit next 6 mos.	79.1	80.4
M (*SD*) readiness quit (1-5)	4.7 (.5)	4.6 (.5)
M (*SD*) goal importance (0-100)	81.8 (15.1)	80.6 (15.4)
M (*SD*) goal confidence (0-100)	82.2 (18.5)	82.0 (19.3)
M (*SD*) concern weight gain (1-10)	6.7 (2.9)	6.7 (3.0)
M (*SD*) days ≥ 5 drinks past yr.	19.9 (44.0)	16.3 (34.4)

***Note*: No baseline differences were statistically significant**

Outcomes (7-day window)

3-month follow-up: 92.1% of participants

- BCAP = 46.8% Nonsmokers Completers Only: χ^2 (df = 1, N = 292) = 4.63, p = .031
- PP = 34.4% Nonsmokers Intent-to-Treat (BCAP = 41.8%; PP = 32.7%): χ^2 (df = 1, N = 317) = 2.79, p = .060

6-month follow-up: 90.2% of participants

- BCAP = 39.2% Nonsmokers Completers Only: χ^2 (df = 1, N = 286) = 0.24, p = .357
- PP = 36.4% Nonsmokers Intent-to-Treat (BCAP = 35.4%; PP = 32.7%): χ^2 (df = 1, N = 317) = 2.79, p = .346

12-month follow-up: 86.1% of participants

- BCAP = 46.8% Nonsmokers Completers Only: χ^2 (df = 1, N = 273) = 2.93, p = .056
- PP = 34.4% Nonsmokers Intent-to-Treat (BCAP = 33.5%; PP = 23.9%): χ^2 (df = 1, N = 317) = 3.60, p = .038

Analyses of booster effects, and of the relationship between outcomes, weight change and drinking reduction are ongoing.

*This study is supported by a grant from the Peer Review Medical Research Program (DAMD17-00-1-0296) , The opinions expressed on this document are solely those of the author(s) and do not represent an endorsement by or the views of the United States Air Force, the Department of Defense, or the United States Government.